SPEAKER BIOGRAPHIES
(alphabetical order)

Lori Adels, PhD
Executive Vice President of Regulatory, Experien Group, LLC
Lori joined Experien Group in 2012 as a highly regarded medical device executive with over 25 years of industry experience. She is an expert in the development and execution of regulatory and clinical strategies for global medical device commercialization. Prior to Experien Group, Lori was the Vice President of Clinical and Regulatory Affairs for the Heart Valve Therapies Division of Edwards Lifesciences, playing a pivotal role on the divisional management team and serving on corporate strategy teams for new product development and acquisitions. Lori has also been the Vice President of Regulatory and Quality for Endovascular Technologies (EVT) and a strategic regulatory consultant for a number of successful medical device companies, including Smart Therapeutics, APTUS, AtriCure and Sadra Medical. She has managed U.S. and international clinical trials as well as regulatory submissions for cardiovascular, cardiopulmonary, neurostimulation, orthopedic, intensive care and respiratory devices. Lori earned a BA from the University of Pennsylvania in the Biological Basis of Behavior and a PhD in Biological Sciences with an emphasis in Neuroscience from the University of California, Irvine.

Karen Becker
Managing Director, Translational & Regulatory Sciences, Precision for Medicine
Karen M. Becker, PhD, joined Precision for Medicine in December 2012 as Managing Director of the Translational and Regulatory Sciences Practice, which was established to provide value-added scientific and regulatory solutions for development, marketing authorization, regulatory compliance, and stewardship of innovative healthcare products. Dr. Becker is an industry leader with over 25 years of experience serving hundreds of clients in a broad range of therapeutic areas, focusing on scientific and regulatory services to companies operating at the intersection of science and public policy. Successful resolution of client matters is achieved through application of sound science, reliance on leading clinical and scientific expertise, and a commitment to outstanding quality and service.

Precision for Medicine is a unique development and commercialization services company that was engineered from inception to help innovators address the needs of the new, evolving healthcare market. Precision for Medicine provides a wide range of strategic services, including scientific and global regulatory strategy, market access and reimbursement planning, biorepository services, and companion diagnostic program management.

Prior to Precision for Medicine, Dr. Becker was President of IndigoBay Ventures LLC, a management consulting firm providing scientific and regulatory services to healthcare companies and investors. She was the Founder and Chief Executive Officer of Becker & Associates Consulting, Inc., a leading full-service scientific and regulatory affairs consulting firm, until its acquisition. She has published original research in pharmacology and drug development, numerous publications on FDA regulation, textbooks on the design of clinical trials for medical devices, and the PLI Medical Device Law and Regulation Answer Book. Dr. Becker is an Adjunct Associate Professor at Georgetown University, where she teaches public health policy and biotechnology management. She received a BS in Biological Chemistry from the University of Maryland at College Park, and a PhD in Pharmacology from the University of North Carolina School of Medicine.
Michael J. Billig  
Co-Founder & Chief Executive Officer, Experien Group  
Mike co-founded Experien Group in 2003 with his wife and business partner Darlene Crockett-Billig as a full-service consulting firm for the medical device industry. As CEO, Mike provides strategic regulatory guidance to the firm’s clientele, frequently representing companies in FDA interface, notified body negotiations, board of directors’ meetings, due diligence activities and more. Mike’s entire professional career has been involved with regulatory affairs, quality systems, clinical research and general management for medical device companies. He entered the industry in 1973 at Medtronic and went on to work for a number of other successful companies, including Guidant, Oximetrix, Abbott and Syntex. Mike held executive-level positions for over 20 years at early stage start-up companies, including Converge Medical, Systems, CardioThoracic Systems, Cardiometrics, and Timi3 Systems where he was President and CEO. Mike has secured U.S and international regulatory approval for hundreds of medical devices. He has been involved with a variety of product areas, including sterile disposables, electronic instruments, capital equipment and wireless health. Mike has been instrumental with multiple successful IPOs, as well as substantial fundraising and corporate acquisitions. Mike earned his B.S. degree in Microbiology from the University of Minnesota.

Jay Crowley  
Vice President and Practice Lead – UDI, USDM Life Sciences  
Jay Crowley is currently Vice President and UDI Practice Leader at USDM Life Sciences, a leading global professional services firm focused exclusively on providing business process, technology and compliance solutions for the regulated life science industry. Prior to joining the firm in January 2014, Crowley was Senior Advisor for Patient Safety, in FDA’s Center for Devices and Radiological Health. He held a variety of positions over his nearly 27 years at FDA. Jay had primary responsibility for the development and implementation of FDA’s Unique Device Identification System requirements of the 2007 FDA Amendments Act and 2012 FDA Safety and Innovation Act.

Christy Foreman  
CDRH, Director of the Office of Device Evaluations  
Christy Foreman is currently the Director of the Office of Device Evaluation (ODE). ODE is the largest office in CDRH and has recently reorganized into 7 reviewing divisions covering numerous medical specialties including cardiovascular, orthopedic, surgical, neurological, anesthesiology, gastro-renal and ophthalmic. The Office is responsible for reviewing premarket applications and approving clinical studies for medical devices. Before being named to the Director position, she served as the Deputy Director for Science and Regulatory policy in ODE. She also worked in the Office of Compliance for 7 years as the Deputy Director for the Division of Enforcement B and the Branch Chief for the Orthopedic, Physical Medicine and Anesthesiology Devices Branch. Before joining OC, Ms. Foreman spent five years as a reviewer in the Anesthesiology and Defibrillator Devices Group in ODE. Before joining the FDA, Ms. Foreman spent seven years at the Naval Medical Research Institute in Bethesda, Maryland with specific research areas in environmental physiology and neuropharmacology. Ms. Foreman holds bachelors and masters degrees in biomedical engineering from The Catholic University of America.
Mark Gordon

Divisional Vice President, Regulatory Affairs, Abbott Medical Optics

Mark Gordon is the Divisional Vice President, Regulatory Affairs, at Abbott Medical Optics, responsible for leading the global regulatory and government affairs efforts of the AMO business units and geographies. He has over 33 years of experience in the medical device industry, including 25 years in Regulatory Affairs, Clinical Affairs, and Quality Assurance, and 8 years in Research and Development. Mark has previously held the position of Vice President, Regulatory Affairs, Clinical Affairs, and/or Quality Assurance, at Synthes/Johnson & Johnson, Boston Scientific, and Medtronic, as well as early-stage organizations. In these roles, Mark has established a track record of successful leadership, strengthening relationships with regulatory agencies, achieving timely global regulatory approvals, effectively managing preclinical and clinical investigations, and sustaining lean and compliant quality systems. Mark has also previously served as Chairman of the RAPS Board of Directors, Co-Chair of the AdvaMed Technology and Regulatory Group, and member of GHTF SG5. He is a RAPS Regulatory Affairs Fellow accomplishing US and EU RAC, and is a Senior member of ASQ. Mark received a Bachelor’s and Master’s degree in Bioengineering from the University of California, San Diego.

Sonali Gunawardhana

Counsel, FDA Practice Group, Wiley Rein, LLP

SONALI P. GUNAWARDHANA is Of Counsel at the law firm of Wiley Rein LLP in Washington, DC. She draws on her nearly 10 years’ experience as an attorney at FDA to offer clients detailed and practical guidance on how to avoid and resolve FDA regulatory challenges. Ms. Gunawardhana’s practice focuses on the rapidly changing FDA regulatory requirements for bringing pharmaceuticals and medical devices to market; the complex emerging rules applicable to domestic and foreign food manufacturers, suppliers, and importers; clinical trial compliance requirements for drug and medical device studies; and the defense of FDA enforcement actions against drug, device, food and dietary supplement companies, Clinical Research Organizations (CROs), academic medical research institutions and individual researchers. Ms. Gunawardhana received a BA from Syracuse University, a MA from Webster University, a MPH from Boston University, a JD from the University of New Hampshire School of Law and a LLM from Washington College of Law, American University.

Mark B. Leahey

President and CEO, Medical Device Manufacturers Association

Mark Leahey is the President & CEO for the Medical Device Manufacturers Association (MDMA), a national trade association in Washington, DC that represents research-driven medical technology companies. Mr. Leahey's responsibilities include advocating on behalf of the entrepreneurial sector of the medical device industry to Congress, the Food and Drug Administration (FDA), the Centers for Medicare and Medicaid Services (CMS), and other federal and state agencies. He has lobbied for a more reasonable user fee for smaller companies, worked to open access to the hospital marketplace by challenging the exclusionary and anti-competitive nature of certain large group purchasing organizations (GPOs), as well as ensure that medical device technologies are reimbursed adequately. Mr. Leahey currently sits on the Medical Devices Committee for the Food and Drug Law Institute (FDLI) and the Editorial Advisory Board of Medical Product Outsourcing. He is a member of the Massachusetts Bar and a graduate of Georgetown University, the Georgetown Law Center and Georgetown’s McDonough School of Business.
John Manthei
Partner, Latham & Watkins, LLP
John R. Manthei is a partner in the Washington, D.C. office of Latham & Watkins and serves as Global Co-Chair and Washington, D.C. Department Chair of the Healthcare and Life Sciences Practice. His practice focuses on regulatory matters involving the Food and Drug Administration (FDA) for the medical device, pharmaceutical, biotechnology, food and dietary supplement industries in the United States and European Union. Mr. Manthei’s practice includes assisting clients with all aspects of the FDA-regulated product life cycle, including, among others: pre-market development; FDA product submissions; development of market exclusivity strategies; drafting and negotiation of both US and international clinical trial agreements; FDA and Federal Trade Commission (FTC) regulation of marketing and promotion of products; Quality System Regulation and Good Manufacturing Practice requirements (including assisting in third-party audits and drafting SOPs); FDA inspections; recalls; FDA and DEA export and import requirements; and civil and criminal compliance and enforcement.

Prior to joining Latham, Mr. Manthei served as Majority Counsel for the US House of Representatives’ Committee on Energy and Commerce (1998-2000). In this capacity, he counseled the Full Commerce Committee Chairman; the Health and Environment and Oversight and Investigations Subcommittee Chairmen; as well as the House Leadership on matters relating to the FDA and legislation concerning the Federal Food, Drug and Cosmetic Act, the Public Health Service Act, and the Controlled Substances Act. Since 2000, Mr. Manthei has represented the pharmaceutical, biotechnology and medical device industries as counsel in nearly every major FDA legislative initiative. He has also testified before Congress on several occasions involving FDA and DEA regulatory and enforcement matters.

Mr. Manthei serves as outside FDA counsel to the Medical Device Manufacturers Association (MDMA), is a member of the Food & Drug Law Institute’s Advisory Committee for Drugs and Biologics, and has been repeatedly recognized as a leading FDA attorney in Chambers USA: America’s Leading Lawyers for Business. In 2006, he was named as one of the “Top 40 Lawyers Under 40” by Washingtonian Magazine, and has been recognized in Who’s Who in America, Who’s Who in American Law and Who’s Who International.

David Parker
Vice President, Market Access Strategy, Precision for Medicine
Dr. Parker has been active for more than 25 years in the healthcare industry, including 16 years of strategy consulting experience centered on the intersection of reimbursement, health economics, clinical science, and marketing strategy. He currently leads Precision for Medicine’s Market Access consulting practice and provides strategic advisory services to the firm’s biopharma, device, and diagnostics clients. His consulting encompasses all aspects of reimbursement, market access, and evidence development strategy with a particular focus on personalized medicine, molecular and advanced diagnostics, and medical devices.

Preceding his appointment at Precision, he led the Washington office of Boston Healthcare Associates. Before then, he was a senior consulting executive at Covance Market Access Services, where as a Vice President he led the Economic Strategies and Devices/Diagnostics practices. Prior to Covance, Dr. Parker was president of a biomedical consulting firm. Throughout his career, his work has resulted in numerous successful product launches, guided major investment and acquisition decisions, and driven favorable coverage and payment determinations by public and private payers alike.

His consulting career was preceded by eleven years of increasingly-responsible product and marketing management, strategic planning, and business development roles at biotechnology companies ranging from
development-stage to units of Fortune 500 businesses. Early in his career, he conducted research in cell biology at Northwestern University Medical School.

Dr. Parker received a Ph.D. in Cell and Developmental Biology from the Massachusetts Institute of Technology, where he was a National Science Foundation Fellow, and an A.B. with high honors from Princeton University.

**Philip Phillips**  
**President, Phillips Consulting Group, Inc.**  
Philip Phillips is President of PHILLIPS CONSULTING GROUP, LLC. He has 33 years of experience in FDA regulation of medical devices, having focused on the development and implementation of numerous regulatory strategies regarding the design, manufacture and marketing of medical devices in the US. Mr. Phillips brings an in-depth knowledge of a wide range of regulatory matters, including FDA jurisdiction, device classification, clinical trials, and product labeling, including promotion and advertising. During his 24-year FDA tenure, Mr. Phillips streamlined the medical device review processes and launched numerous agency initiatives aimed at enhancing public health while lessening regulatory burden. In addition to serving as the Office of Device Evaluation’s Deputy Director for Science and Regulatory Policy for 12 years, he served as Director of Program Operations, Interim Director for the Division of General and Restorative Devices, Deputy Director for the Division of Ophthalmic Devices and the Chief of the Surgical and Diagnostics Devices Branch in DOD. Mr. Phillips holds a BS in Microbiology from the University of Maryland and a MBA from the George Washington University.

**Heather Rosecrans**  
**Vice President of Regulatory Affairs, MDMA**  
Heather Rosecrans brings more than 30 years of public health and medical device experience to MDMA. Rosecrans continues her commitment to public health at MDMA where she provides strategic consulting services and works with MDMA members to bring innovative devices to patients.

Prior to joining MDMA, Rosecrans served as Director of the 510(k) Pre-Market Notification Staff at the U.S. Food and Drug Administration’s (FDA) Center for Devices and Radiological Health (CDRH). In this role, Rosecrans was responsible for implementing administrative and regulatory policy for the 510(k) Program, the 513(g) Program, Classification and Reclassification, de novo petitions and other premarket regulatory requirements. Rosecrans started her FDA career as a biologist in the agency's Bureau of Medical Devices - prior to the formation of CDRH. In 1980, Rosecrans joined the newly organized CDRH Premarket Application (PMA) Staff. For the next seven years, she coordinated the administrative, scientific and regulatory review of PMAs, product development protocols and associated submissions. In 1987, Rosecrans joined the 510(k) Section of CDRH's Program Operations Staff (POS). In this role, Rosecrans served as a Consumer Safety Officer and was a key contact for CDRH and FDA on 510(k) matters. Rosecrans held this position until 1992, at which time she became Director of the 510(k) Staff. Rosecrans' accomplishments include drafting guidance documents and regulations regarding the 510(k) program, training staff, and assisting in the implementation of the Medical Device User Fee Modernization Act (MDUFMA) and Food and Drug Administration Modernization Act (FDAMA). Rosecrans' extensive experience at CDRH, and specifically the 510(k) office, enabled her to become one of the nation's leading experts on the program. Rosecrans' tenure also allowed her to play a pivotal role in the program's development and reform. Since the program's inception in 1976, more than 120,000 products have been cleared via the 510(k) program. Rosecrans has represented and spoken on behalf of CDRH in multiple forums, including national conferences, FDA advisory committee meetings, and international symposiums. Her published work includes numerous guidance and regulatory documents. She has also worked collaboratively with CMS and other regulatory agencies. Rosecrans holds a Bachelor of Science in Biology from Pfeiffer College in Misenhelmer, NC.
Dr. Daniel Schultz joined Greenleaf Health following a distinguished 35-year career devoted to supporting and advancing Americans’ public health as a physician, teacher, Food and Drug Administration (FDA) official and member of the U.S. Public Health Service (USPHS). He has been recognized many times for his contributions and dedication to public health.

Dan continues his commitment to public health at Greenleaf, where as Senior Vice President for Medical Devices and Combination Products he provides strategic consulting services and works with Greenleaf clients to bring innovative devices to patients.

As Director of the Center for Devices and Radiological Health (CDRH) at FDA from 2004 to 2009, Dan was responsible for seven FDA offices and more than 1,000 agency employees. He led the development, implementation and evaluation of regulatory policies concerning medical devices and radiation-emitting products. He also established national goals and policies to ensure that FDA and U.S. Department of Health and Human Services (HHS) objectives were met.

Dan began his 15-year FDA career in 1994 as a Medical Officer in the General Surgery Devices branch of the CDRH’s Office of Device Evaluation, advancing in 1995 to the position of Chief Medical Officer in the Office of Device Evaluation in the division of Reproductive, Abdominal, ENT, and Radiological Devices. He served as division Director from 1998 to 2001.

Dan became Deputy Director for Clinical and Review Policy in the Office of Device Evaluation in 2001 and Director of the Office of Device Evaluation the following year. Named Director of CDRH in 2004, he remained in that role until stepping down this year.

Prior to joining FDA, Dan served as a member of the U.S. Public Health Service (USPHS). During postings at Indian Health Service hospitals in Arizona and New Mexico, he provided medical care for people living in the Navajo Nation and Indian Pueblos. Dan received multiple awards for his service, including the Public Health Service Outstanding Service Medal.

In addition to his role at Greenleaf, he shares his medical knowledge and experience as Assistant Professor of Surgery at the Uniformed Services University of the Health Sciences and as a member of the Surgical Staff at the National Naval Medical Center, both located in Bethesda, MD.

Dan is a fellow of the American College of Surgeons, a member of the Commissioned Officers Association (COA). He has written and spoken all over the world about regulatory, medical device and public health issues.

A New York City native, Dan is a graduate of the City College of New York. He received his medical degree from the University of Pittsburgh and is Board-certified in Surgery and Family Practice.
Steven Silverman  
**Director, CDRH, Office of Compliance**  
Steve Silverman is the Director of CDRH’s Office of Compliance. In this role, he oversees a staff of more than 190 scientific and regulatory personnel who assure compliance with the medical-device related provisions of the federal Food, Drug, and Cosmetic Act and its implementing regulations. Mr. Silverman also leads cross-cutting strategic planning initiatives and represents CDRH on global compliance programs. He comes to this position from his role as Assistant Director of the Center for Drug Evaluation and Research’s Office of Compliance, where he helped lead a staff that applied federal laws and regulations governing the development, manufacture, labeling, and marketing of human drugs.

Before joining the Center for Drugs, Mr. Silverman served as an Associate Chief Counsel in FDA’s Office of Chief Counsel. Mr. Silverman’s government service includes four-plus years as a trial attorney with the U.S. Department of Justice’s Tax Division, which he joined following his tenure with the Federal Trade Commission’s Financial Practices Division. He began his career in private practice.

Mr. Silverman received his undergraduate degree *cum laude* from the University of Michigan. He attended the University of Pennsylvania law school, where he graduated *cum laude* and was an editor of the University of Pennsylvania Law Review.

Elaine Tseng  
**Partner, King & Spalding**  
Elaine Tseng is a partner with King & Spalding’s FDA & Life Sciences Practice Group. After prior practice with the group as an associate and partner-elect, Ms. Tseng rejoined the group following service as Regulatory Counsel at the Food and Drug Administration, where she received the Department of Health and Human Services Secretary’s Award for Distinguished Service and other FDA honors. In her practice, Ms. Tseng advises medical device, pharmaceutical, and biotechnology companies on a variety of FDA approval, compliance, and enforcement matters. Ms. Tseng has been invited to speak on topics of FDA regulation for groups including the American Conference Institute (ACI), the Advanced Medical Technology Association (AdvaMed), the Biotechnology Industry Organization (BIO), and the Center for Business Intelligence (CBI). She received her law degree from Harvard Law School and her undergraduate degrees from Cornell University.

John Weiner  
**Associate Director for Policy, Office of Combination Products**  
John Barlow Weiner is the Associate Director for Policy in the Food and Drug Administration’s Office of Combination Products, which is tasked with the classification and assignment for regulation of therapeutic products (drugs, devices, biological products, and combination products), and with ensuring the sound and consistent regulation of combination products.

Prior to joining OCP, Mr. Weiner was an Associate Chief Counsel in FDA’s Office of Chief Counsel, advising the agency on various issues including regulation of drugs and cross-cutting topics including the regulation of products that use nanotechnology. Before coming to FDA, Mr. Weiner was in private practice in the areas of food and drug, environmental, and related aspects of public international and trade law. He has published and lectured on topics in all three areas.
Mr. Weiner received a BA from Princeton University and a JD with honors from the Columbia University School of Law.

**Barbara Zimmerman**  
**Deputy Director, CDRH, Office of Device Evaluation**  
Barbara A. Zimmerman is Deputy Director of the Office of Device Evaluation at the Food and Drug Administration. Barbara's responsibilities include negotiating, implementing, and monitoring the performance of the Medical Device User Fees. She has worked for the FDA in the Office of Device Evaluation for 18 years. She has a Bachelor's Degree in Electrical Engineering from Drexel University.